510(K) Summary, K122787

Simple Diagnostics®

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Contact person: Muhammad Arif

DEC 6 2012

Date prepared: October 17, 2012

1. Trade Name: Comfort EZ™ Insulin Syringe
Common Name: Insulin syringe
Classification Name: Syringe, piston, product code FMF, Regulation: 880.5860
Class of device: Class II.

2. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : Feel-ject Insulin Syringe made by Feel Tech (Korea) K070917

3. Description of device: The Comfort EZ™ insulin syringe consists of a calibrated hollow barrel which can contain the medication and the distal end of barrel is fixed with needle. The needle cannot be exchanged after assembling because needle is fixed in the barrel nozzle lumen. The plunger and gasket are the same shape as the conventional insulin syringes. The needle cap cover is intended to provide physical protection to the needle tube. The cap is color coded orange, same as equivalent insulin syringes. The syringes are available in 28 through 31 gauge needle sizes, in 0.3 ml/cc, 0.5 ml/cc and 1 ml/cc capacities. They are supplied with a sterile fluid path, (EO), non-toxic, and non pyrogenic, for single use only, disposable. The devices operate on the principles of common piston syringes.

4. Intended use: For the injection of U100 insulin.

5. Technological characteristics: The Comfort EZ™ Insulin Syringes and the predicate devices have identical technological characteristics and perform the same way as common piston syringes. The materials utilized remain the same as the predicate, mainly stainless steel for the needles and polypropylene for the barrel components. These syringes are EO sterilized and are for single use only.

Comparison Table.

Device Name	Feel-ject Insulin Syringe made by Feel Tech (Korea) K070917	Comfort EZ™ insulin syringe
Intended Use	For the injection of U100 insulin.	Identical
Method of Use	1. To expose plunger, remove large white cap. 2. To expose needle, pull small orange cap straight off, being careful not to bend needle. 3. To measure correct dosage, align top edge of plunger tip with your dosage mark on the syringe scale. 4. Use syringe only once. To prevent misuse after injection, use sharps container	Identical

Device Name	Feel-ject Insulin Syringe made by Feel Tech (Korea) K070917	Comfort EZ™ insulin syringe
Type	Type 8 of ISO8537:1991(E); syringe with fixed needle tube and fitted with protective end cap.	Identical
Barrel Marking	Scale: conforms to ISO 8537:1991(E)	Identical
Lubricant	Polydimethysiloxane	Identical
Lubricant amount (mg/cm^2)	0.25 max	Identical
Barrel transparency	Haze 25% max. (2mm sheet)	Identical
Reuse	For only use	Identical
Biocompatibility	Conforms to ISO 10993-1	Identical
Materials	1) Plastic parts: polypropylene	Identical
	2) Gasket : natural rubber	Identical
	3) Packing film : Polyethylene film	Identical
Sterility	Sterilized by ethylene oxide gas SAL = 10^{-6}	Identical
Packaging	Each syringe is individually packaged in a Tyvek peel pouch. There are 10 syringes packaged in a poly bag. There are 10 poly bags packaged in a cardboard box.	Ten syringes are packaged in a poly bag. There are 10 poly bags packaged in a cardboard box. (i.e. 100 syringes)

6. **Performance: Bench and standards compliance testing was performed.**
Bench testing included: Biocompatibility: (ref ISO 10993) Cytotoxicity, Maximization, Intracutaneous Toxicity, Hemolysis, Systemetic toxicity, and Pyrogen Testing,
Mechanical testing: Hub/needle bond strength. ISO 7894:1993
Sterility testing (ISO 11607 and ISO 11135) including EO residues testing (ISO 10997-7.)
Standards compliance: ISO 8537 Sterile, Single-Use Syringes, with or without Needle, for Insulin Scale: conforms to ISO8537:1991(E)
The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.

7. **Clinical testing: Not required to establish equivalence.**

8. **Conclusion: The Comfort EZ™ insulin syringe complies with applicable standards for insulin syringes, uses identical materials and manufacturing methods to the predicate, and has been tested for biocompatibility and performance characteristics. The syringe has the identical intended use to the predicate. We therefore conclude that the Comfort EZ™ syringe is substantially equivalent to the predicate device.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 6, 2012

Simple Diagnostics, Incorporated
C/O Mr. Daniel Kamm, P.E.
Kamm & Associates
8870 Ravello Court
Naples, Florida 34114

Re: K122787
Trade/Device Name: Comfort EZ™ Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 8, 2012
Received: September 11, 2012

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

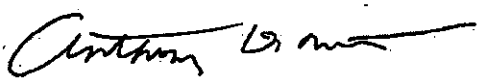
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Director of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122787

Device Name: Comfort EZ™ Insulin Syringe

Indications For Use:

The Comfort EZ™ disposable sterile insulin syringes are intended for injection of U100 insulin only.

Prescription Use ____ **AND/OR** **Over-The-Counter Use** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Gail G. Gantt

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Date: 2012.12.06 15:10:58 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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